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MRLs are like potatoes - Complex

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MRL Basics

An MRL is:

- Maximum Residue Limit

An Import Tolerance (IT) is:

- MRL based on foreign residue data, that facilitates trade

A Codex MRL or CXL is:

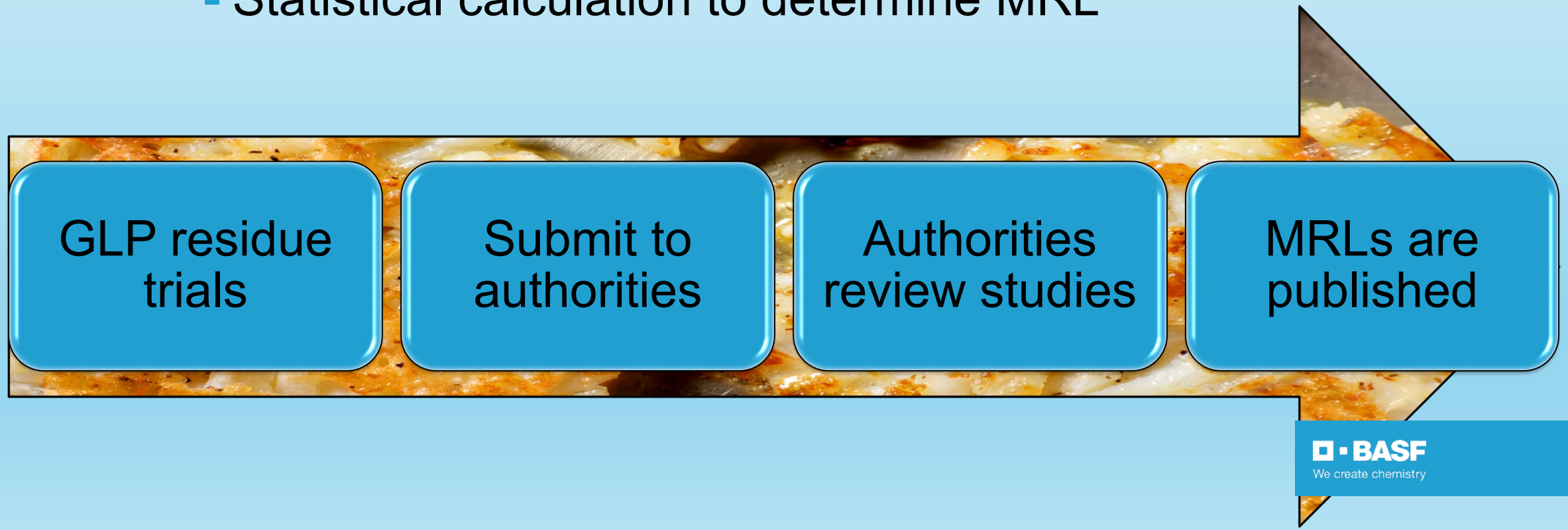
- An MRL set by Codex

All are established by:

- Residue trials following the maximum labelled use directions

How Are MRLs Established?

- GLP Residue trials following the label
  - Processing
- Statistical calculation to determine MRL



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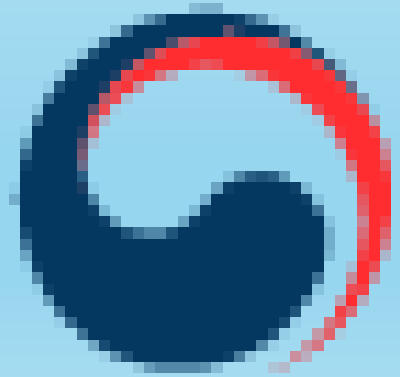
How are MRLs established?



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What an MRL is NOT

MRL ≠ Measure of Safety

$$Animal\ studies \rightarrow No\ Adverse\ Effect\ Level \rightarrow Reference\ Doses \rightarrow Risk\ Cup$$

$$Plant\ Residue\ studies \rightarrow Residue\ results \rightarrow math \rightarrow MRLs$$

$$Residues\ in\ crops:$$

Maximum reference dose (acute, chronic, etc)

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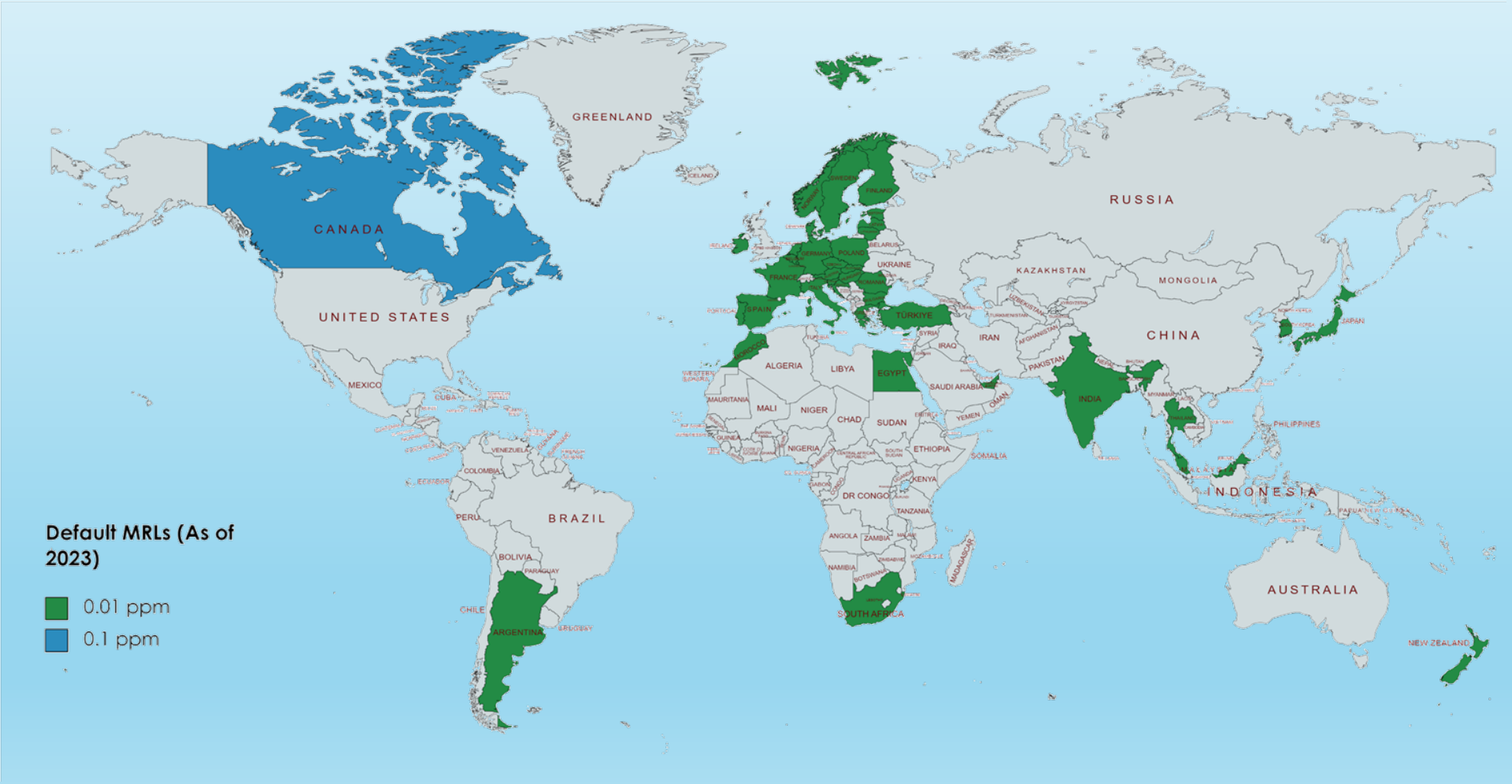
Default MRLs?



Valid For Trade

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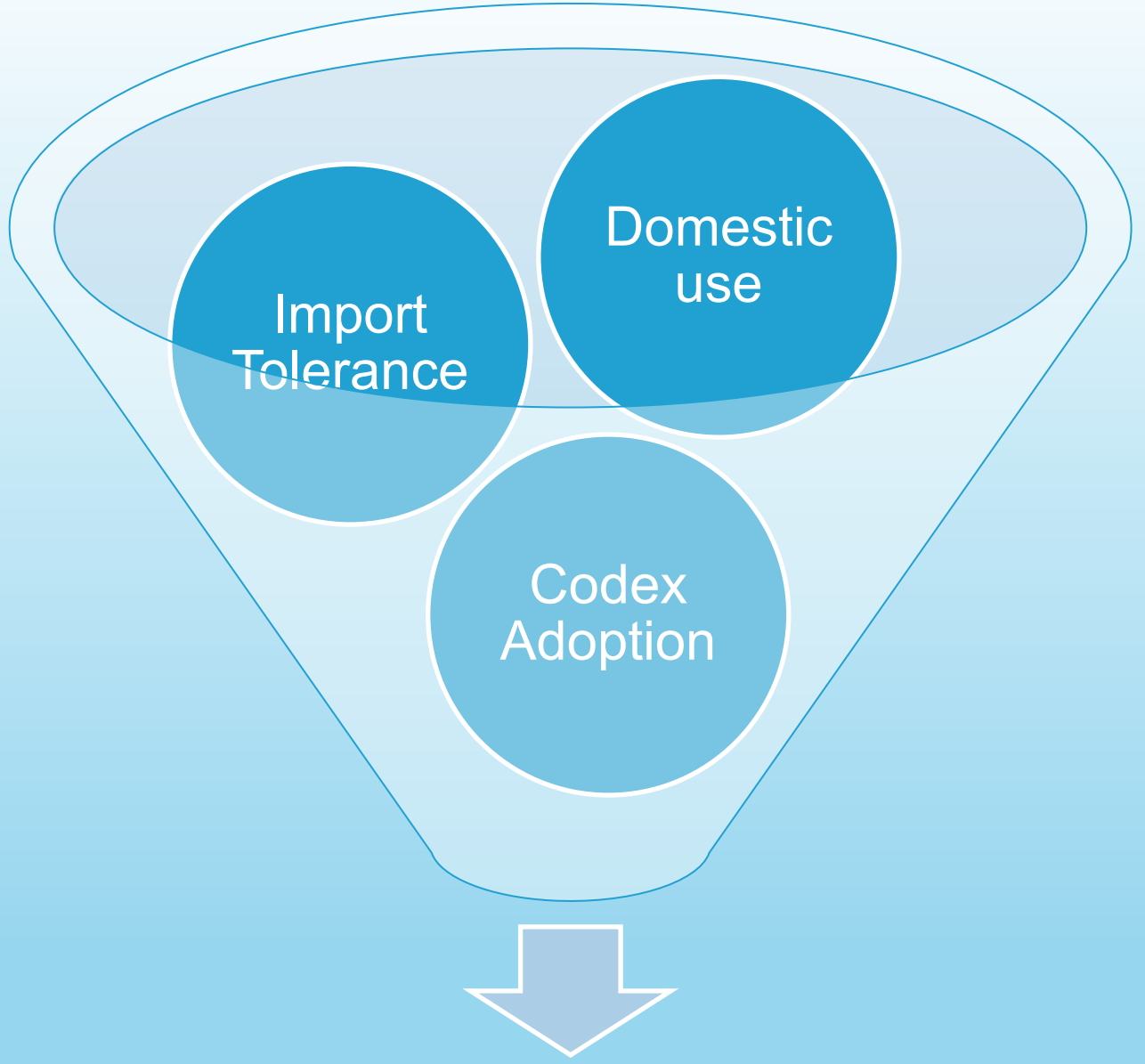

MRL

When is disharmony a problem?

- Residues in a food item found to exceed an importing country's MRL may be found to be in violation and may not be allowed to enter commerce
  - Important word: **RESIDUES**

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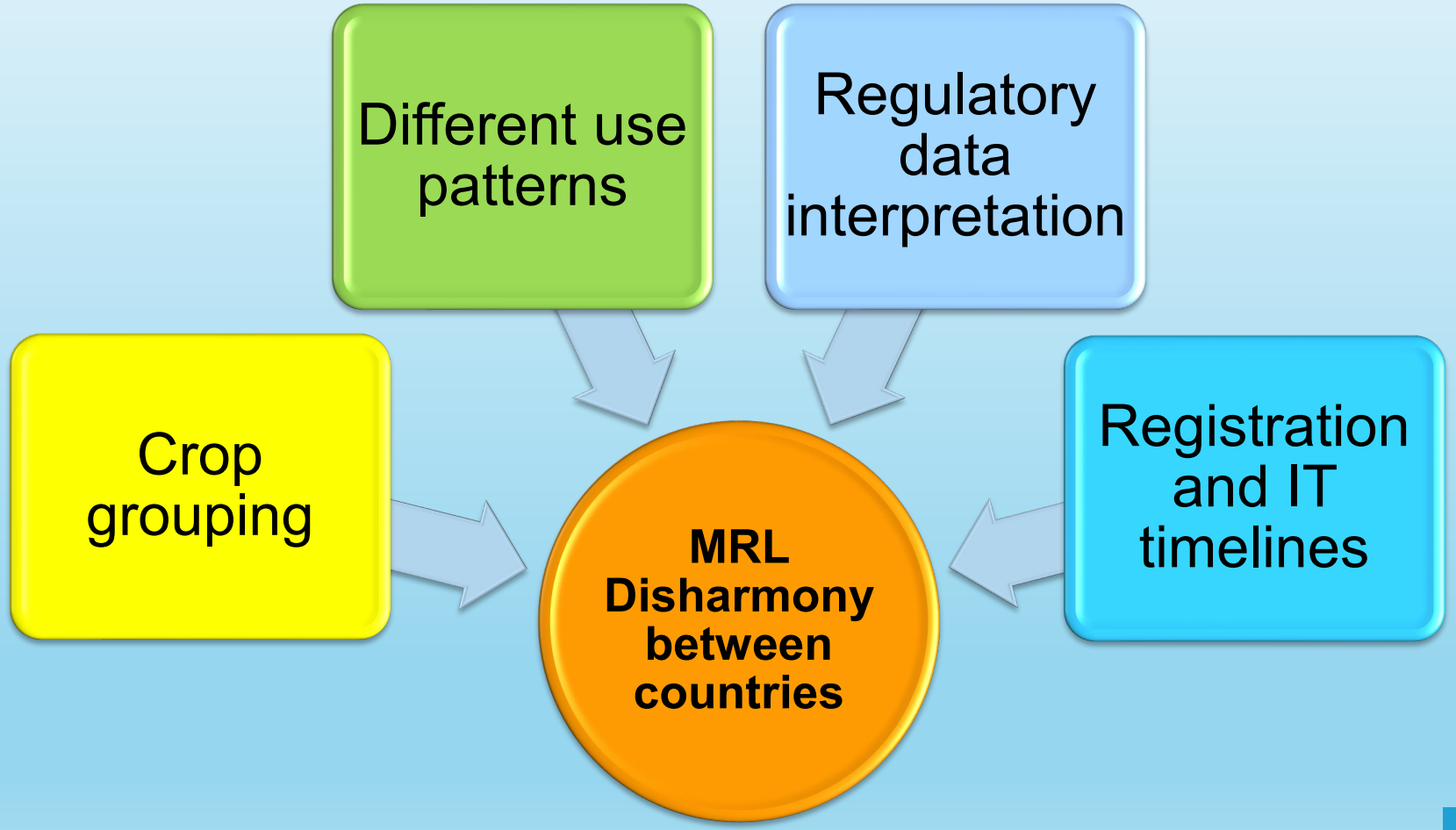
MRL Disharmony



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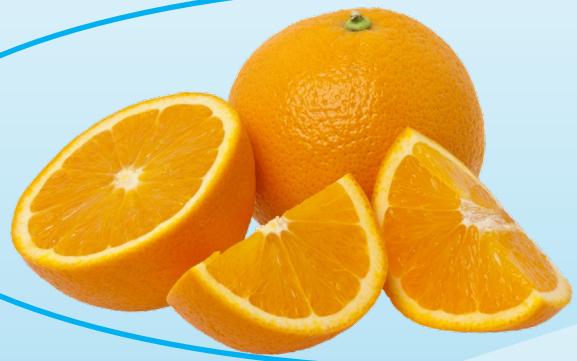
Crop Grouping

US MRL
0.2 ppm



0.1 ppm

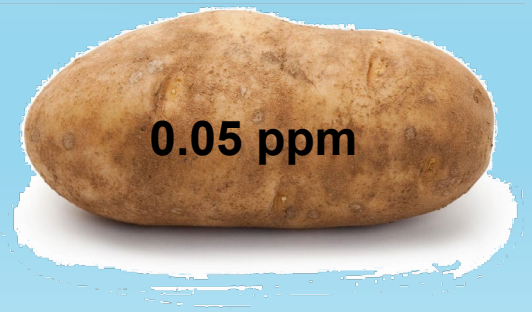
0.1 ppm

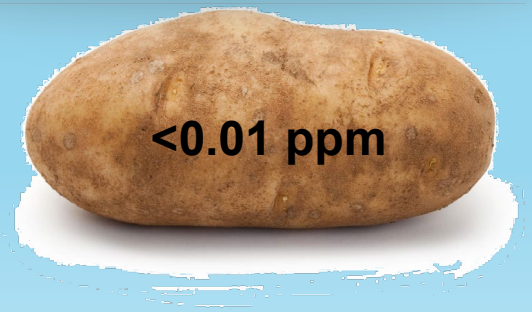
0.2 ppm

Taiwan MRLs

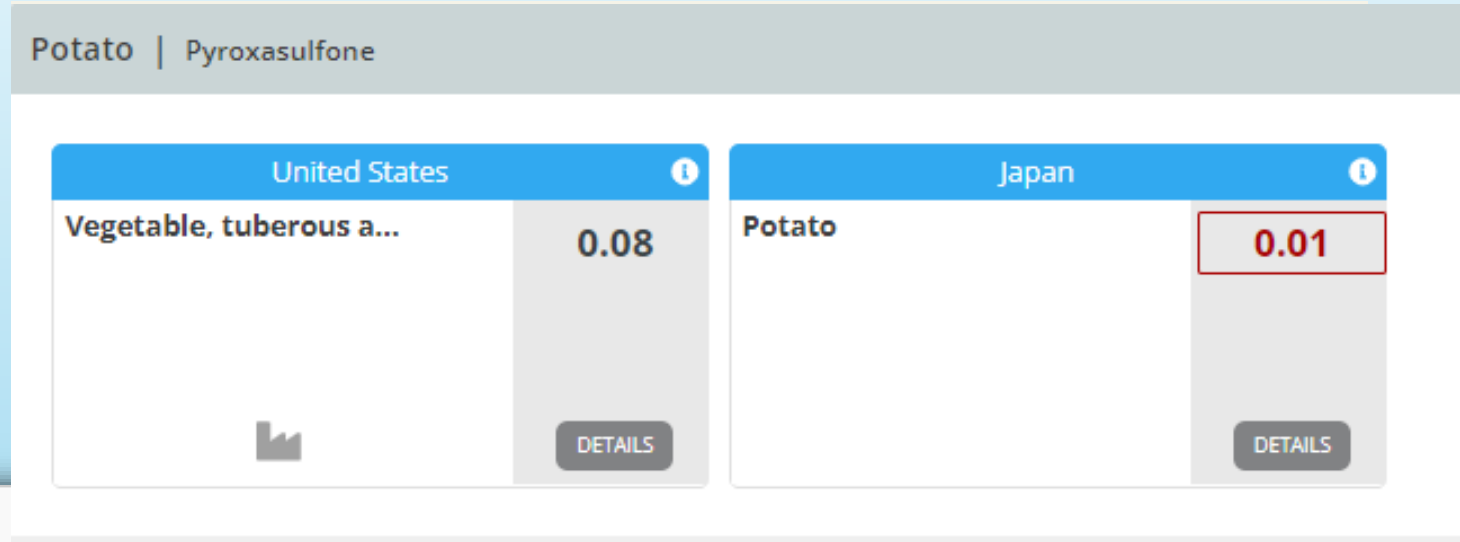
Same Data, Different Conclusions

Different Use Patterns





Regulatory Data interpretation



Potatoes

0.08 ppm

Residue Definition

Pyroxasulfone: 3-[-5-(difluoromethoxy)-1-methyl-3- (trifluoromethyl)pyrazol-4-yl-methylsulfonyl]- 4,5-dihydro-5,5-dimethyl-1,2-oxazole including the metabolites (5-difluoromethoxy-1-methyl-3- trifluoromethyl-1H-pyrazol-4-yl)-methanesulfonic acid, 5-difluoromethoxyl-1- methyl-3-trifluoromethyl-1H-pyrazole-4- carboxylic acid, (5-difluoromethoxy-3- trifluoromethyl-1H-pyrazol-4-yl)- methanesulfonic acid, and 3-[1-carboxy-2-(5,5- dimethyl-4,5-dihydroisoxazol-3- ylthio)ethylamino]-3-oxopropanoic acid (expressed as parent equivalents)

Regulation

MRL Database (25 February 2020) consulted via PMRL2019-38

Effective Date: February 25, 2020

Potato

0.01 ppm

Residue Definition

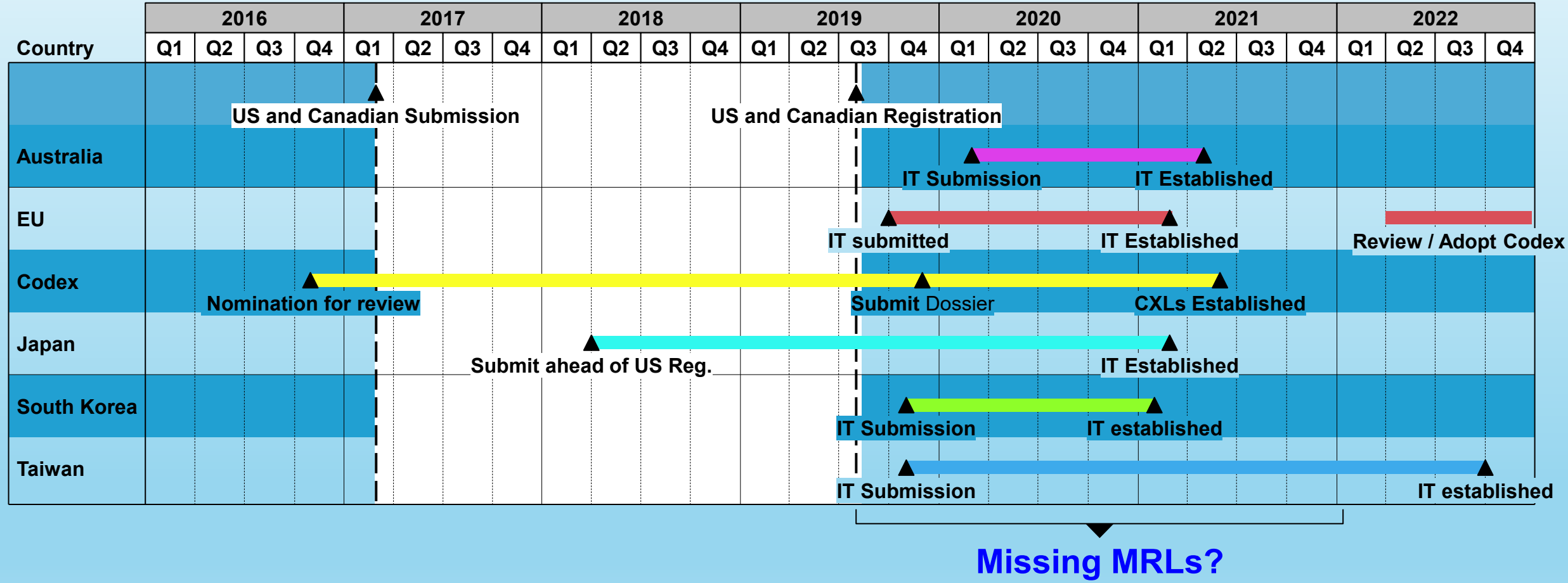
Pyroxasulfone

Regulation

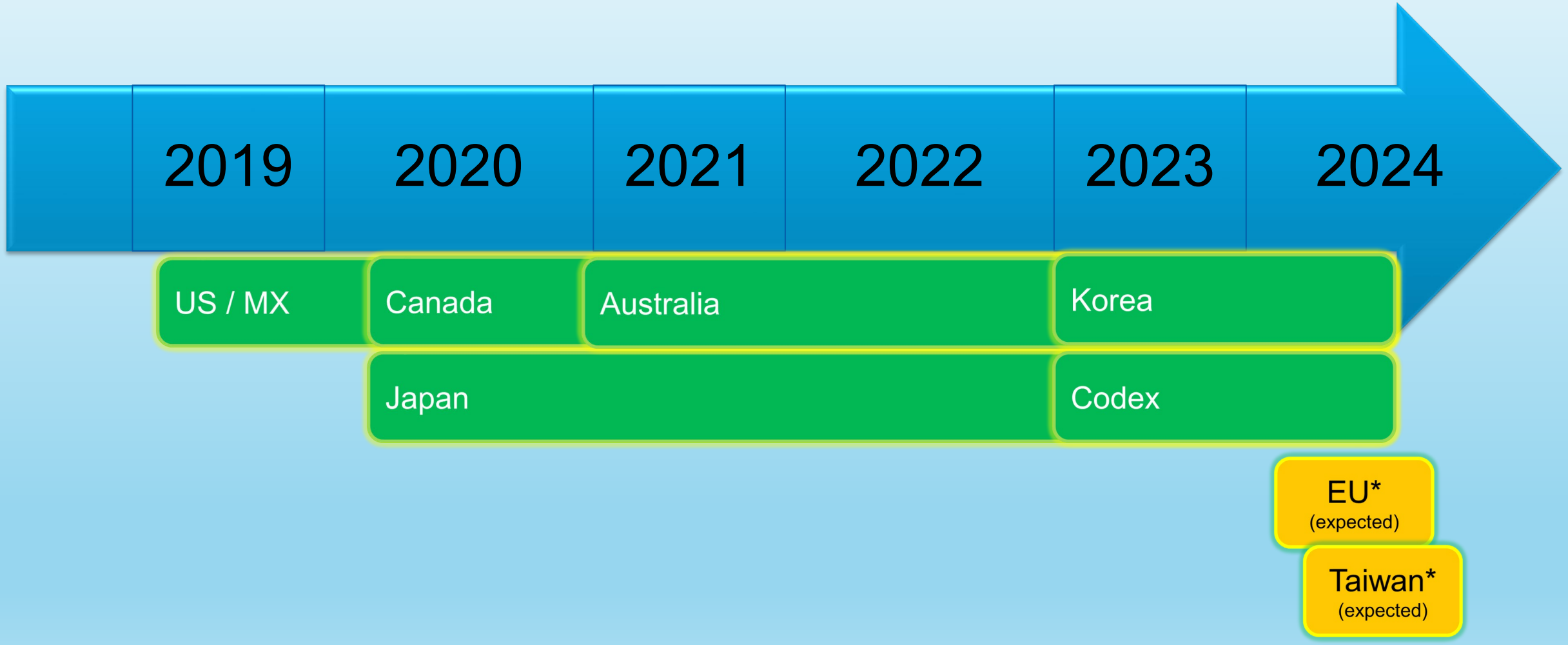
Ministry of Health, Labour and Welfare Food Safety. Update 0630 No. 1, June 30, 2020

Effective Date: June 30, 2020

MRLs are like potatoes – Lots of good things happen that aren't seen



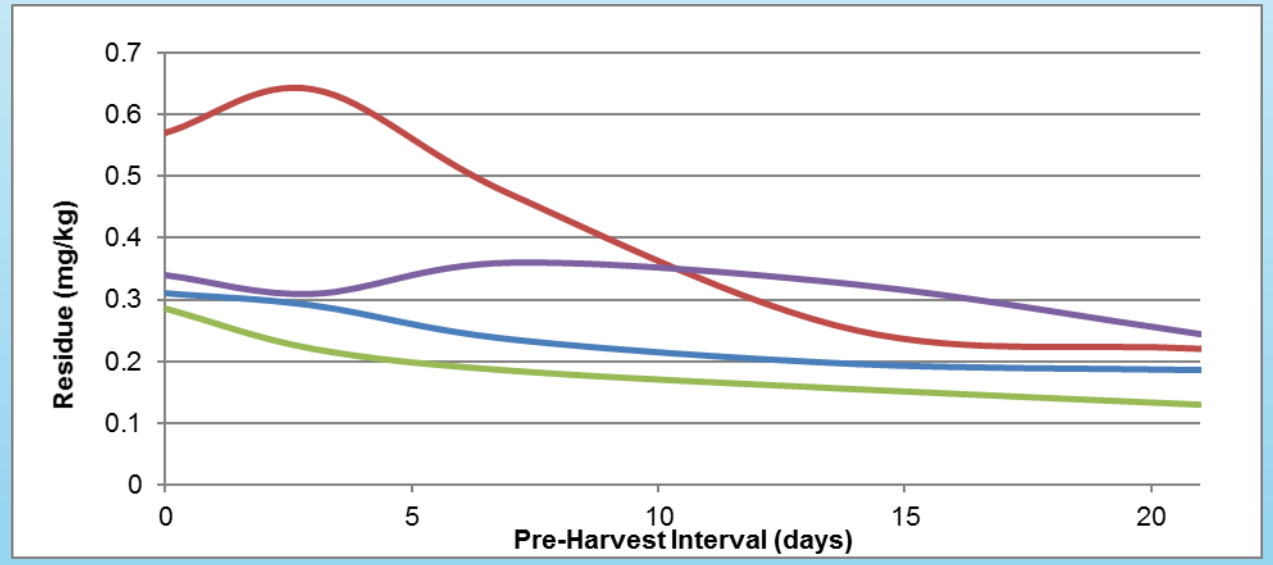
Endura® Pro (Revysol®) Example

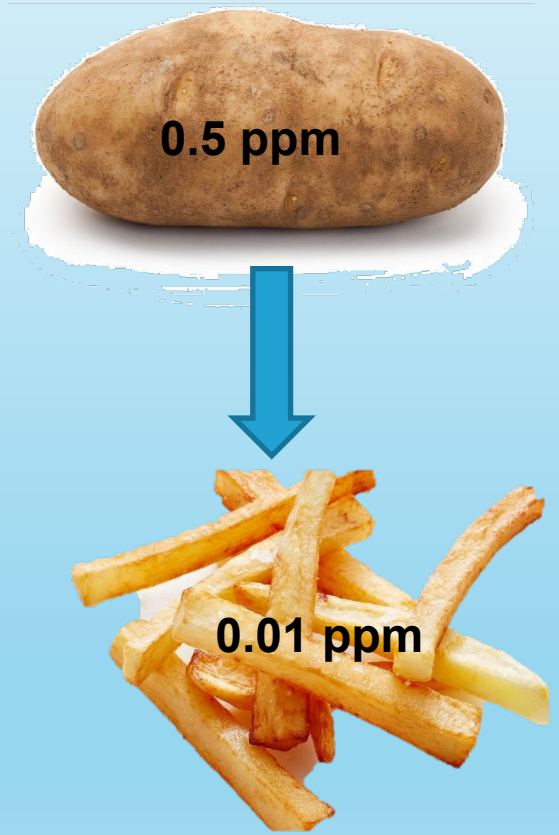


What can be done?

TIME

SCIENCE





Processing
Factor = 0.02

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Check Before you Ship

MRL in Place

Residues trade compliant

Please remember MRLs may change and growers/exporters are responsible for checking a reliable data source to ensure an MRL is in effect prior to export. This information is accurate to the best of our knowledge at the time it is provided. BASF shall not be liable for any damages whatsoever related to MRL compliance issue

In Summary, MRLs are…

Necessary	• Evaluated for human health • Allow trade of commodities with residues
Complex	• Regulations differ between countries • Regulations and interpretations change
Challenging	• Often 2-3 years from registration to MRLs in export markets • Challenges in data review and timing

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